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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/634,038	08/08/2000	Gregory S. Keller	206066	5444

7590 02/11/2005

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 02/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/634,038	Applicant(s) KELLER, GREGORY S.	
	Examiner William H. Matthews (Howie)	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 16, 17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 16, 17 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>1-13-05</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. The finality of the last office action is hereby withdrawn.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 16,17 are rejected under 35 U.S.C. 102(e) as being anticipated by Naughton US Pub. No. 2002/0038152 A1.
3. Naughton discloses in abstract and paragraphs 14-17,21-22,28-29,33-34,46-56,64,67, and 74 a method of corrective surgery of a vocal cord defect comprising the steps of retrieving cells from the patient's skin, culturing the cells in vitro with collagen to create extracellular matrix, separating the cells, and implanting the matrix by injection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4,6-9,11,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boss Jr US PN 5,591,444 in view of Daniels et al. US PN 3,949,073.

Boss Jr discloses in line 22 of col. 3 through line 37 of col. 6 a method of corrective surgery comprising the steps of obtaining dermal fibroblast cells from the patient, culturing the cells in vitro, and implanting the cells by injection or engraftment. Boss Jr discloses example applications of the method such as depressed scars and wrinkles, but not expressly for vocal cord and furthermore lacks the express disclosure of including collagen or a phosphate buffered solution. Daniels et al. teaches a method of corrective surgery in lines 17 of col. 2 through line 59 of col. 5 for depressed scars and wrinkles as well as vocal cord defects. Furthermore, Daniels et al. discloses a rinsing step utilizing a phosphate buffered saline solution and the use of collagen to cause rapid colonization after implantation.

Therefore it would have been obvious to one of ordinary skill in the art to modify the method disclosed by Boss Jr by utilizing a phosphate buffered solution to rinse the cells, incorporate collagen in order to cause rapid colonization after implantation, and apply the method to tissue of the vocal cord to correct vocal cord defects as taught by Daniels et al.

6. Claims 1,2,5,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agerup US PN 5,633,001 or Hubbard US PN 5,922,025 in view of Vacanti US PN 5,041,138.

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Each of Agerup (lines 8-28 of col. 28) and Hubbard (line 52 of col. 3 through line 3 of col. 4) disclose a method of repairing a vocal cord defect by autologous adipose cell injections. Agerup and Hubbard both lack the express written disclosure of culturing adipose cells in vitro before injection. Vacanti et al. teaches in abstract culturing cells in vitro before implantation in order to ensure adequate cell volume and density for the cells to survive in vivo.

Therefore it would have been obvious to one of ordinary skill in the art to modify the method disclosed by Agerup or Hubbard by culturing the cells in vitro before implantation as taught by Vacanti et al. in order to ensure adequate cell volume and density for the cells to survive in vivo.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boss Jr US PN 5,591,444 in view of Daniels et al. US PN 3,949,073 as applied to claim 1 above, and in further view of Osbourne et al. US ub 2004/0156833.

The method disclosed by Boss Jr. as modified by Daniels et al. meets the limitations of claim 10 as described above, and discloses using bovine serum but lacks the express written disclosure of using the patient's serum for culture medium.

Osbourne et al. teaches in paragraph [0009] that it is well known in the art to use a patient's own serum for culturing cells for implantation to ensure biocompatibility of the implanted cells.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Boss Jr, as modified by Daniels et

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al., to include culturing the cells in the patient's own serum before implantation to ensure biocompatibility of the implanted cells.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



WHM
January 13, 2005



CORRINE McDERMOTT
JURY PATENT EXAMINER
TECHNOLOGY CENTER 3700